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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/438,206	11/12/99	SHI R	7024-427-PUR

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EXAMINER	
HUI	
ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/438,206	SHI ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Applicant's election with traverse of claims 1-15 for examination in Paper No. 7, mailed on December 7, 2000, is acknowledged. The traversal is on the ground(s) that both inventions are classified in the same classification and therefore there is no undue burden of search to the Office. This is not found persuasive because even though the inventions are classified in the same classification, the field of search is diverse. See MPEP § 808.02(c). Note that the search field for a composition containing certain ingredients is different from the search field for a particular method of use employing a composition containing the same ingredients. The search is not limited to the patent files. Therefore, the search for the compositions and methods encompassed by the claims presents an undue burden to the Office. See also the restriction requirement mailed November 7, 2000.

As discussed in the restriction requirement of November 7, 2000, distinctness between the claimed inventions is seen. The products as claimed, i.e. composition comprising polyalkylene glycols and potassium channel blockers, can be used in materially different processes for example one can use these agents in a process to treat cerebral ischemic condition and liver ischemic condition.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyethylene glycol and other polyalkylene glycols specifically mentioned in the specification such as polymethylene glycols, polypropylene glycols, polybutylene glycols, polypentylene glycols, polyhexylene glycols, polyheptylene glycols, polyoctylene glycols, polynonylene glycols, and polydecylene glycols, does not reasonably provide enablement for any other polyalkylene glycols (See page 11, line 29 – page 12, line 3). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There is no adequate direction provided by the applicant as to how to select any other suitable polyalkylene glycols to be used in the invention to treat injured spinal cords or spinal cord tissue. Furthermore, the instant specification does not provide any working examples to point out how other polyalkylene glycols besides polyethylene glycol, and the polyalkylene glycols disclosed in page 11, line 29 – page 12, line 3, can be used successfully in the invention to treat injured spinal cords or spinal cord tissue. Please note that examples 1 to 6 disclosed in the specification only demonstrate the use of polyethylene glycol for treating an injured spinal cord.

Moreover, it is known in the art that different compounds may have different potency and activity because of the structural and conformational differences in the

compounds. Therefore a different polyalkylene glycol other than polyethylene glycol, and the polyalkylene glycols disclosed in page 11, line 29 – page 12, line 3, may yield a totally different result. Due to this unpredictability, it would prevent the skilled artisan from selecting a species of polyalkylene glycol to retain the desired function of the instant invention to treat an injured mammalian spinal cord or spinal cord tissue, as currently claimed, without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in scope since it is unclear where claim 6 ends. Every claim should end with a period. See MPEP 608.01(m).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bittner et al. (Brain Research, 367, 1986: 351-355. from the Information disclosure Statement received April 1,2000), Krause and Bittner (Proc Natl Acad Sci USA, 87, 1990: 1471-5. from the Information Disclosure Statement received April 1,2000), and Krause et al. (Brain Research, 561, 1991: 350-3. from the Information Disclosure Statement received April 1,2000) in view of Potter et al. (Clin Invest Med, 19(4), Suppl.: S80, #533) and Ishikawa (WO97/35577, an english language equivalent, USPN 6,090,823 also provided).

Brittner et al. teaches the utilization of PEG to rejoin a severed axon of mammalian cell line (abstract). Krause and Bittner teaches the direct application of a predetemined concentration and molecular weight of polyethylene glycol (PEG) to restore the mophological continuity of severed axons. (See abstract; p.1471, col. 2, last paragraph) Krause et al. teaches the direct application of a predetemined concentration and molecular weight of polyethylene glycol to restore the functional continuity of a crushed axon. (See p.350, last paragraph; p.350, col. 2, last paragraph to p.351, col. 1, first paragraph)

The concentration and molecular weight of polyethylene glycol used in the references are 50% w/w of PEG (MW = 1-10kDa). (See Krause and Bittner, p.1471, col. 2, last paragraph) and 60% w/w containing 20% 2000Da PEG and 40% 4000Da PEG in distilled water. (See Krause et al., p.353, col. 2, last paragraph)

The references suggest that the application of PEG may be used for the reconnection and functional recovery of severed and crushed myelinated mammalian

axons. (See Brittner et al., p.355, first column; Krause and Bittner, p.1471, col. 2, last paragraph; Krause et al., p.353, last paragraph)

The references do not expressly teach that 4-aminopyridine, the potassium channel blocker, can be combined with the axon injury treating method of the primary references to treat spinal cord cell injury. In addition, the references do not teach the specific molecular weight of PEG, i.e., 400-3500 daltons, employed herein.

However, Potter et al. teaches the use of 4-aminopyridine to treat spinal cord injury. (See #533)

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine 4-aminopyridine with polyethylene glycols, which have molecular weight range of 400-3500 daltons, together to treat mammalian spinal cord injury.

One having ordinary skill in the art would have been motivated to combine the two agents together in methods to treat spinal cord injury because combining two agents which are known to be useful to treat spinal cord injury individually into a single method that is useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Moreover, the range of molecular weight taught by Krause et al. and Krause and Brittner encompass the molecular weight range of the instant invention. Optimization of result effect parameters is obvious as being within the skill of the artisan.

Ishikawa provides further motivation for the claimed method of treatment employing PEG since he teaches that PEG is known to be useful in spinal cord injury

treatment compositions administered into the spinal cord (See page 4, line 16-24; also USPN 6,090,823, col.3, line 53-59).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
February 26, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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